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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,048	03/11/2004	David J. Blair	32093-2	4980

7590 04/14/2009  
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EXAMINER

KOPPIKAR, VIVEK D

ART UNIT PAPER NUMBER

3686

MAIL DATE DELIVERY MODE

04/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/798,048

**Applicant(s)**

BLAIR, DAVID J.

**Examiner**

VIVEK D. KOPPIKAR

**Art Unit**

3686

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

1. Claims 1-22 have been examined in this application. This communication is a Final Office Action in response to the "Remarks" filed on February 24, 2009.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-12, 15-17 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Number 5,553,609 to Chen.

(A) As per claim 1, Chen teaches a method, comprising:  
providing a server coupled to a computer network (Chen: Figure 7 and Col. 11, Ln. 20-36); receiving a patient follow-up request from a practitioner (Chen: Col. 6, Ln. 37-44); entering data in a patient information database maintained by the server in response to the patient follow-up request (Chen: Col. 6, Ln. 37-46); assigning a patient contact to a health care monitor from the server over a computer network (Chen: Col. 6, Ln. 62-66);  
receiving patient data over the computer network from the health care monitor

about the patient contact (Chen: Col. 2, Ln. 60-Col. 3, Ln. 21 and Col. 7, Ln. 3-16); storing the patient data in the patient information database (Chen: Col. 7, Ln. 2-11); and sending the patient data to the practitioner from the patient information database (Chen: Col. 7, Ln. 22-25).

(B) As per claim 2, in Chen the health care monitor is a pharmacist (Note: The Office takes the position that the “other health care professionals” discussed in Chen includes pharmacists) (Chen: Col. 6, Ln. 37-44).

(C) As per claim 3, in Chen the health care monitor is remotely located relative to the server, and said assigning includes designating several different patient contacts for the health care monitor from the server over the computer network (Chen: Col. 6, Ln. 62-66).

(D) As per claim 4, in Chen the health care monitor contacts the patient by telephone to perform the patient contact (Chen: Col. 6, Ln. 38-43).

(E) As per claim 5, in Chen there is a step of providing an administrative site coupled to the server by the computer network; providing at least a portion of the patient data to a program sponsor through the computer network (Chen: Col. 7, Ln. 3-16); and evaluating the patient data to determine patient compliance (Chen: Col. 7, Ln. 3-10).

(F) As per claim 6, Chen teaches a method of providing a server for storing a patient information database (Chen: Fig. 7 and Col. 11, Ln. 20-36); generating an assignment of a patient contact to a health care monitor with the server (Chen: Col. 6, Ln. 62-66); sending the assignment to the health care monitor through a computer network coupled to the server (Chen: Ln. 6, Ln. 62-66); in response to the patient contact by the health

care monitor, receiving patient data through the computer network from the health care monitor (Chen: Col. 2, Ln. 60-Col. 3, Ln. 21 and Col. 7, Ln. 3-16); storing the patient data received from the health care monitor in the patient information database (Chen: Col. 7, Ln. 2-11); and sending the patient data to a health care provider for the patient from the patient information database (Chen: Col. 7, Ln. 22-25).

(G) As per claim 7, Chen teaches that the generating is performed in response to a request from a health care provider (Chen: Col. 6, Ln. 30-43 and Col. 6, Ln. 62-66).

(H) As per claim 8, Chen teaches that the patient receives a prescription from the health care provider and the request from the health care provider is generated to determine compliance of the patient with the prescription (Chen: Col. 7, Ln. 37-44 and Col. 9, Ln. 40-48).

(I) As per claim 9, Chen teaches that the health care monitor is a pharmacist remotely located relative to the server (Chen: Col. 6, Ln. 30-43).

(J) As per claim 10, the method of Chen includes the pharmacist providing counseling to the patient regarding a drug treatment (Chen: Col. 9, Ln. 19-34 and Col. 9, Ln. 40-48).

(K) As per claim 11, the method of Chen includes entering a patient diagnosis and one or more drug codes into the patient information database, and designating the health care monitor to be a pharmacist (Chen: Col. 6, Ln. 30-43; Col. 7, Ln. 3-16; Col. 12, Ln. 54-Col. 13, Ln. 3 and Col. 14, Ln. 47-59) (Note: Chen teaches entering drug names into the

patient information database which the Office takes the position as including the step of entering one or more drug codes into the patient information database.)

(L) As per claim 12, the method of Chen includes the health care monitor performing the patient contact by telephone (Chen: Col. 6, Ln. 30-43).

(M) As per claim 15, the method of Chen includes the health care provider adjusting medical treatment of the patient in response to the patient data after sending (Chen: Col. 9, Ln. 19-34).

(N) As per claim 16, this claim is substantially similar to Claims 1 and 6 and is therefore rejected on the same as this claim, which is set forth above. The only difference is that this claim includes a computer accessible device and this is taught by Chen (Col. 1, Ln. 64-Col. 2, Ln. 28 and Col. 6, Ln. 22-50).

(O) As per claim 17, Chen teaches that the logic is in the form of programming instructions (Chen: Col. 5, Ln. 39-42).

(P) As per claims 19-22, these claims are substantially similar to claims 1-12 and 15-17 and are therefore rejected on the same basis as these claims, which is set forth above. The only difference is that these claims are directed towards a system and this is taught by Chen (Col. 6, Ln. 22-50).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen, as being applied to Claim 6, above, and in even further view of US Patent Number 6,101,478 to Brown.

(A) As per claim 13-14, Chen does not teach a health care monitor asking assigned questions of the patient during the patient contact nor does Chen teach providing the patient data to a drug outcome study, however, this feature is taught in Brown (Col. 5, Ln. 50-63 and Col. 6, Ln. 46-63). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the teachings of Chen with these aforementioned teachings from Brown with the motivation of having a personalized means of monitoring patients and with the motivation of having a means of generating data to a pharmaceutical company could later use for research purposes, as recited in Brown (Col. 5, Ln. 50-63).

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen, as applied to Claim 16, above, and in even further view of US Patent Number 5,960,405 to Trefethan.

(A) As per claim 18, Chen does not teach that the logic is in the form of one or more signals transmittable over the computer network, however, this feature is taught by Trefethan (Col. 6, Ln. 26-65). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Chen with this aforementioned teaching from Trefethan with the motivation of having an alternate means of transmitting information.

### *Response to Arguments*

7. Applicant's arguments filed on February 24, 2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed in the same order as they were presented in the "Remarks" section filed on February 24, 2009.

(1) Applicants argue that Chen does not teach the step of "receiving a patient follow-up request from a practitioner". However, Chen teaches contacting a patient by telephone in response to a predetermined event or condition (Chen: Col. 9, Ln. 33-56) and the Office takes the position that this disclosure teaches the step of "receiving a patient follow-up request from a practitioner."

(2) Applicants argue that Chen fails to teach the steps of "sending the patient data to the practitioner from the patient information database" and "providing at least a portion of the patient data to a program sponsor through the computer network." However, the Chen discloses this very feature (Col. 16, Ln. 65-col. 17, Ln. 17). This cited disclosure of Chen teaches that a health care professional may obtain vital data regarding a patient from a computer (e.g. patient information database) and the Office takes the position that this aforementioned disclosure in

Chen is the equivalent of "sending patient data to the practitioner from the patient information database" and "providing at least a portion of the patient data to a program sponsor through the computer network."

(3) Applicants argue that Chen does not teach that one of the health care monitors is a pharmacist. However, the Office takes the position that it is inherent in the health care industry that the term health care professionals includes pharmacists because pharmacists are primary health care providers who are licensed through licensing exams administered by professional boards.

(4) Applicants argue that Chen does not teach the step of "generating an assignment of a patient contact to a health care monitor with the server." Applicants also argue that Chen fails to teach the step of "generating an assignment of a patient contact to a health care monitor from a patient information database maintained by the server in response to a request from a health care provider." However, Chen teaches these very features (Col. 6, Ln. 22-50) and (Col. 11, Ln. 22-24). With regard to the step of "generating an assignment of a patient contact to a health care monitor from a patient information database maintained by the server in response to a request from a health care provider" applicants appear to be claiming that this step is performed off-line since this step takes place in response to a request from a health care provider and is therefore not automatic and therefore this step can be said to take place "off-line" and Chen discloses this very feature (Col. 11, Ln. 22-24).

(5) Applicants argue that Chen does not teach "wherein the patient receives a prescription from the health care provider and the request from the health care provider is

generated to determine compliance of the patient with the prescription." However, the Office takes the position that this feature is taught in Chen (Col. 9, Ln. 40-48). This portion of Chen states that a Master Monitoring Station (MMS) is used to monitor a patient's compliance to a medical treatment. In Chen it is the health care provider who operates the MMS and therefore the Office takes the position that the request to perform such monitoring is made by the health care provider from whom the prescription was received because in Chen, the MMS system is meant to be used precisely by health care providers rather than any other parties (Chen: Col. 2, Ln. 38-50).

(6) Applicants argue that Chen does not teach entering drug codes, however, the Office would like to point out that Chen teaches the step of entering a drug name (Chen: Col. 14, Ln. 53-60) and the Office takes the position that this drug name would somehow have to be entered into the system of Chen and somehow be represented by characters, either by the entire full name of the drug or by a shorthand abbreviation and therefore, the Office takes the position that either the step of entering the entire drug name or an abbreviation for the drug in Chen comprises the step of entering drug codes.

(7) Applicants argue that Chen fails to disclose one or more practitioner computers and one or more health care monitor computers. Applicants also argue that Chen fails to disclose a computer network coupled to the server, the administrative computer, the one or more practitioner computers, the one or more health care monitor computers and a program sponsor computer coupled to the computer network. However, the Office would like to point out that Chen discloses one or more practitioner computers and one or more health care monitor

computers (Chen: Col. 6, Ln. 38-43). Chen also teaches a computer network coupled to a server (Figure 7) and an administrative computer (denoted as Supervisory Control Center (SCC) --Item 102 in Figure 7 and Col. 11, Ln. 20-36 of Chen). Finally, Chen teaches a program sponsor computer coupled to the computer network because in Chen the (SCC) appears to administer the system and method disclosed by Chen and therefore the Office takes the position that the (SCC) in Chen functions as a program sponsor computer since it administers the system and method (e.g. program) disclosed by Chen.

(8) The Office has provided support for all of the occurrences of the Official Notice taken in the last Office Action, dated October 21, 2008.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone number for

this group is (571) 273-8300 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/  
Examiner, Art Unit 3686  
4/14/2009

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
Group Art Unit 3686